REMARKS

This is in response to the Office Action mailed on 10 August 2006 in which pending claims 1-14 stand rejected.

Herewith Applicants amend claims 1, 2, 4, 6, and 8, and cancels no claims, and adds no new claims.

Entry and favorable consideration of the amendments and remarks presented herewith is respectfully requested.

Objections to Claims

Objections to claims 1, 2, and 4 were lodged because the Examiner required correction of the phraseology used to the hemodynamic monitor means." Herewith, Applicants amend claim 1, 2, and 4 as suggested by the Examiner.

Objection to the Specification

The specification was objected to because it allegedly fails to provide proper and antecedent basis for the monitoring functions of the monitoring and/or stimulating means.

Applicants respectfully disagree and traverse the stated objection.

Claim Rejections under 35 U.S.C. §112

Claims 1, 3, 5, 7, 9, 10, and 14 are rejected under the first paragraph of section 112 as failing to comply with the enablement requirement. The Examiner alleges that the monitoring and/or stimulating device is not expressly disclosed.

Applicants respectfully disagree and traverse the stated rejections.

Applicants herewith amend paragraph three ("0003") so that the co-pending, co-owned, and incorporated-by-reference application to Warkentin (now U.S. Pat. No. 7,027,866 is accurately identified.

Applicants that while portions of Warkentin could be expressly incorporated it would be unnecessary in light of the inherent and express disclosure contained in the application as-filed. For example, at paragraphs

0021 and 0022 the precise monitoring and stimulation devices are specifically identified, to wit:

[0021] The present invention was tested in the therapy for a 58 year-old male patient having cardiovascular risk factors that included cigarette smoking, hypertension and a family history of coronary artery disease and heart failure. In 1993 the patient suffered from an infero-lateral myocardial infarction (MI) that was treated by thrombolysis. Post infarction echocardiography revealed a moderately enlarged left ventricle (LV) with a left ventricular ejection fraction (LVEF) of 45%. The patient underwent complete revascularization by coronary artery by-pass grafting (CABG) in August 1994. In the post surgery period the patient developed symptoms of severe heart failure and the LVEF decreased to 15-20%. Medical therapy with diuretics, enalapril, carvedilol, ASA, pravastatin and digoxin led to significant clinical improvement. In May 1999 the patient was included in a clinical trial conducted on behalf of Medtronic, Inc. of Minneapolis, Minnesota, U.S.A. (for the Chronicle® implantable hemodynamic monitor). This trial was a study to evaluate the technical accuracy and reliability of an implantable hemodynamic monitor (IHM) over time. Three months later, in August 1999, the patient had a minor stroke. The corresponding IHM information revealed an episode of paroxysmal atrial fibrillation (AF) and anticoagulant treatment with warfarin was started. During the following eight months the patient was hospitalized three times for a troponin positive acute coronary syndrome caused by paroxysmal AF. Each time the patient could be successfully cardioverted, but the patient's clinical status deteriorated steadily. In May, 2000 echocardiography measurements showed significantly enlarged ventricles with a left ventricular end-diastolic diameter (LVEDD) of 81 mm, LVEF of about 10%, mitral insufficiency (grade $^2/_4$) and tricuspid regurgitation (grade $^3/_4$). The patient was listed for heart transplantation.

[0022] Due to symptomatic bradycardia, first-degree heart block (P-Q interval of 260 ms) and a left anterior hemi-block with a QRS duration of 120 ms, a bi-ventricular pacemaker was implanted (the InSync® brand pacemaker

> manufactured by Medtronic, Inc.). The Chronicle® brand IHM (manufactuered by Medtronic, Inc. Model 9520) allows continuous, ambulatory hemodynamic recording using a pressure sensor placed in the right ventricular (RV) outflow tract. Heart rate (HR), activity and several pressure or pressure related parameters are measured and stored in the memory of the subcutanously implanted device. The data collection can be programmed to various follow-up periods that regulate the storage interval. In this disclosure RV systolic pressure (RVSP), RV diastolic pressure (RVDP), estimated pulmonary artery diastolic (ePAD) pressure (10,11), rate-of-change pressure (dP/dt) and HR measured both acutely (storage interval of two seconds) and ambulatory (storage interval of six minutes) are described (emphasis added).

Thus, the claimed subject matter is clearly supported with the application as-filed and the rejection of claims , 3, 5, 7, 9, 10, and 14 (and the objection to the specification too).

Applicants respectfully request that the Examiner accept the foregoing response to the rejections (and objections) as, in light of same, the rejections (and objections) should be properly withdrawn.

Claim Rejections under 35 U.S.C. §103

Pending claims 1-14 stand rejected as allegedly obvious over the '623 patent to Kieval et al. (Kieval) in view of the '324 patent to Carlson (Carlson).

Applicants respectfully traverse the rejection.

First of all, regarding independent claim 1, the Examiner argues that Kieval provides a majority of disclosure contained in the claim but suggests that Carlson stands for the proposition that hemodynamic data be collected during periods of rest and periods wherein said patient is performing the activities of daily living.

However, Carlson in fact does not support or share the Examiner's interpretation; to wit (from column 2, line 55 to column 3, line 7):

> The calculated value associated with pulse pressure may be analyzed by the microprocessor over a preselected number of cardiac cycles and for a plurality of preselected timing intervals, wherein the timing interval is a measured time between at least one of intrinsic and paced stimulations of pre-selected chambers of the heart. The value associated with pulse pressure corresponding with each timing interval is then compared to determine which timing interval results in the greatest pulse pressure. The pacer may then automatically reset the timing interval to this "maximum" timing interval.
>
> **The analysis and comparison of the accelerometer signal preferably occurs when the patient is at rest**, the quiescent period. The accelerometer signal may also be used to determine the period of quiescent activity. **Analyzing the accelerometer signal during the period of quiescent activity minimizes motion artifact in the accelerometer signal. Further, analyzing the signal during the period of quiescent activity allows the measurements to be taken during relative steady state hemodynamic conditions** (with emphasis added).

Furthermore, contrary to the assertion of the Examiner, Carlson refers "activity" later in the document and this reference reinforces that Carlson does not endeavor to monitor the accelerometer during periods of activity. To wit (from column 4, line 59 to column 5, line 8):

> The accelerometer 16 is positioned within the casing of the cardiac stimulator or pacer and is coupled to the microprocessor based controller 18 through an analog/digital convertor 26 and filters further described below. The accelerometer 16 provides a signal that is processed to provide a non-intrusive measure of pulse pressure during a cardiac cycle. The casing of the cardiac pacer 10 is implanted in a surgically made pocket, typically in either the left or right shoulder region of the patient. By positioning the accelerometer 16 in the casing (not shown) of the cardiac pacer 10, the accelerometer 16 generates a global signal associated with various atrial and ventricular events. A globalized signal is preferred over a localized signal (a signal transmitted from an accelerometer in direct contact with an outer wall of the heart). **The signal from the accelerometer 50 may also be used to evaluate levels of physical activity, *thereby identifying periods in which physical activity is low*** (with emphasis added).

And yet another citation to Carlson supports Applicants' position (from column 7, lines 10-19):

> The microprocessor receives a digitized accelerometer signal from the accelerometer. A portion of this signal represents the level of physical activity of the patient. An initial test may be made to determine whether the physical activity is less than a predetermined amount X, which is

> indicative of a patient at rest. When the patient is resting, the accelerometer readings are less subject to noise and motion artifacts.
>
> When the physical activity is less than the predetermined amount X, the A-V interval index m is then set to 1…(with emphasis added).

It is thus highly apparent that Carlson collects accelerometer signal (data) during periods of rest (or "quiescent activity") to minimize motion artifacts in the signal. Since no such motivation exists with respect to a pressure sensor and if an accelerometer were used (as in Carlson) the combination would fail (i.e., be rendered inoperable), the Examiner has failed to posit a *prima facie* obviousness rejection against claim 1. Since claims 2-4 depend, directly or indirectly from independent claim 1, they too are not rendered obvious by the proposed combination of Kieval and Carlson and should be allowed.

Based on the same rationale, independent claim 5, claims 6-13 depending therefrom and independent claim 14 also cannot fairly be said to be rendered obvious by the posited combination of Kieval and Carlson.

Conclusion

Applicants respectfully suggest that all pending claims are now in condition for allowance and earnestly solicit the Examiner to issue a Notice of Allowance in due course so that the claimed invention can pass to timely issuance as U.S. Letters Patent.

The Examiner is invited to contact the undersigned with any questions regarding the instant application and this Response.

Respectfully submitted,

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Date

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